REMARKS

The present application is directed to methods of detecting anti-tumor autoantibodies in an individual by detecting complexes formed by the binding of autoantibodies in a sample from the individual with tumor marker proteins. The tumor marker proteins used in the claimed methods are isolated from a bodily fluid obtained from a body cavity or space in which a tumor is or was present in a cancer patient.

Claims 9-10, 13-14 and 19-38 were previously cancelled. Claims 15-18 were previously withdrawn but are now rejoined for examination. Claims 1-8, 11-12, 15-18, 39-41 and 43-44 are currently under examination. No new matter is introduced.

Summary of Interview with Examiner

Applicants thank the Examiner for the interview conducted on August 23, 2010. Examiner Bristol and Jamie Greene (applicants' representative) were present in person during the interview. The interview participants discussed the double patenting, enablement and written description rejections and differences between the claimed compositions and the teachings of the publication cited by the Examiner, namely Robertson *et al.* (PCT Application No. WO 99/58978, hereinafter "Robertson"). These differences are also discussed in this Response. The interview participants discussed potential claim amendments, and applicants have incorporated several suggestions for claim amendments discussed during the interview in this Response.

Double Patenting

The Examiner maintained the provisional rejection of Claims 1-8, 11 and 12 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1, 4 and 8 of copending Application No. 10/417,633 ("the '633 application") in view of Robertson *et al.* (WO 99/58978).

As mentioned and discussed previously, applicants respectfully wish to defer the filing of a terminal disclaimer in response to this rejection until allowable subject matter in the '633 application has been established.

The Examiner newly rejected Claims 1-8, 11-12, 15-18 and 39-44 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-22 of US Patent No. 7,402,403. Applicants respectfully wish to defer the filing of a terminal disclaimer in response to this rejection until allowable subject matter in this application has been established.

Rejection under 35 U.S.C. §112, first paragraph

The Examiner asserted that the rejection of Claims 1-8, 11-12, 15-18 and 39-44 under 35 U.S.C. §112, first paragraph, was maintained for lack of enablement. Applicants respectfully traverse the rejection.

The Examiner asserts that the present application does not enable the use of the claimed methods for detecting any autoantibody against any tumor antigen for any cancer, for any neoplastic change or early carcinogenic change in asymptomatic patients, for measuring recurrence of cancer or assessing prognosis for a treatment therapy.

Applicants respectfully submit that the claimed method claimed is not a method for detecting **any** autoantibodies, it is a method of detecting cancer-associated anti-tumor autoantibodies in a sample from an individual. In addition, the claimed method is not a method for detecting any autoantibody against **any** tumor antigen, it is a method of detecting cancer-associated anti-tumor autoantibodies against one or more tumor marker proteins prepared from a bodily fluid from a body cavity or space in which a tumor is or was present in one or more cancer patients.

Applicants note that dependent Claim 2 specifies that the immunoassay is carried out using a **panel** of two or more immunoassay reagents, dependent Claims 3-8 specify the patient or subject from whom the sample is taken and the type of information (such as diagnosis, early neoplastic or carcinogenic change, etc.) concerning that patient or subject

provided by detecting cancer-associated anti-tumor autoantibodies and dependent Claims 15-18 list **specific tumor markers**. The Examiner states that the claimed method is enabled for MUC1/breast cancer, CA125/ovarian cancer, and MUC1/sarcoma, yet rejects Claims 15 and 16, which specifically name MUC1 and MUC16 (previously known as CA125), for lack of enablement.

Applicants respectfully request that the Examiner indicate if any of the dependent claims would be allowable if rewritten in independent form containing all the limitation of the base claims from which they depend.

For at least the foregoing reasons, applicants respectfully submit that the claims are enabled and request withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

Rejection under 35 U.S.C. §102(b)

The Examiner maintained the rejection of Claims 1-8, 11-12 and 39-44 under 35 U.S.C. §102(b) as anticipated by Robertson *et al.* (WO 99/58978, hereinafter "Robertson"). Applicants respectfully traverse.

As explained by Applicants' representative during the interview, Robertson can be distinguished from the claims of the present application because the present claims specify the **source** of the tumor marker proteins (immunoassay reagents) used in the immunoassay. Specifically, Robertson fails to teach the use of tumor marker proteins prepared from a bodily fluid from a body cavity or space in which a tumor is or was present in one or more cancer patients as claimed in the present application.

The claims of the present application clearly distinguish between the term "bodily fluid sample", which describes the **sample** being tested, and the "bodily fluid" **source** from which the tumor marker proteins are prepared. When read in context, the Robertson publication also distinguishes between these two terms.

For example, on page 6, lines 1-13 of the Robertson publication, Robertson describe the bodily fluid **sample** that can be tested as follows:

> Because the assay method of the invention [is] **performed on a sample of bodily fluids** taken from the patient[,] it is essentially non-invasive and can be

> repeated as often as is thought necessary to build up a profile of the patient's immune response throughout the course of disease. As used herein the term 'bodily fluids' includes plasma, serum, whole blood, urine, sweat, lymph, faeces, cerebrospinal fluid or nipple aspirate. The type of bodily fluid used may vary depending upon the type of cancer involved and the use that the assay is being put to. In general, it is preferred to perform the method on samples of serum or plasma. (emphasis added)

When read in full and in context, the term "bodily fluid" referenced in this section of the Robertson publication clearly describes only the bodily fluid **sample** being tested by the assay, **not** the biological fluid source from which the tumor marker antigens are prepared.

Lines 9-22 on page 7 of the Robertson publication teach the **source** of the tumor marker antigens:

> The panel assay of the invention uses a panel of tumour marker-related antigens. The panel may be tailored to detect a particular cancer, or a cancer at a particular stage of development. The tumour marker antigens may be wild type or mutant tumour marker proteins isolated from samples of biological fluid from normal individuals, or from cancer patients or from cell lines expressing the tumour marker protein or they may be full length recombinant tumour marker proteins, viral oncogenic forms of tumour marker proteins or antigenic fragments of any of the aforementioned proteins.

This section of the Robertson publication **fails** to teach or even suggest the preparation of tumor marker proteins from a bodily fluid from a body cavity or space in which a tumor is or was present in one or more cancer patients as claimed in the present application.

Page 8, lines 21-27 of the Robertson publication also describe the **source** of the tumor marker antigens:

> As aforementioned, the assays can be formed using tumour marker antigens which are forms of these proteins isolated from human bodily fluids or from cultured cells or antigenic fragments thereof or full length or truncated recombinant proteins or antigenic fragments thereof.

This section follows a listing of preferred markers for inclusion into the panel and is merely summarizing the statement made on page 7. **No** mention is made of the preparation of tumor marker proteins from a bodily fluid from a body cavity or space in which a tumor is or was present in one or more cancer patients as in the present claims.

On page 14, line 30, to page 15, line 5 of the Robertson publication, Robertson teaches **serum** from advanced breast cancer patients as the preferred source of MUC1 protein as follows:

> MUC1 isolated from the **serum** of patients with advanced breast cancer is therefore **preferred** for use as antigen in the panel assay method and the single marker assay methods described herein. (emphasis added)

Robertson clearly states that the preferred **source** of the tumor marker antigen, MUC1, is patient **serum**, which is explicitly excluded from Claim 1.

In light of the foregoing remarks, applicants respectfully submit that Robertson fails to anticipate the claimed method and request withdrawal of the rejection of the claims under 35 U.S.C. §102(b).

Rejection under 35 U.S.C. §112, first paragraph

The Examiner rejected Claims 1-8, 11-12, 15-18 and 39-44 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Applicants respectfully traverse the rejection.

Applicants respectfully submit that the present application contains working examples, clearly describes the source of antigen as being from a bodily fluid from a body cavity or space in which a tumor is or was present in one or more cancer patients, lists at least five exemplary bodily fluids useful as sources of the tumor marker protein (ascites, pleural effusion, seroma, hydrocoele and wound drainage fluid – paragraph [0028]), and lists at least 12 tumor marker proteins (MUC1, MUC16 (CA125), c-myc, c-erbB2, p53, ras, BRCA1, BRCA2, APC, PSA, CEA and CA19.9 – see paragraph [0062] and the examples).

For at least the foregoing reasons, applicants respectfully submit that the claims are sufficiently supported by the specification and request withdrawal of the written description rejection under 35 U.S.C. §112, first paragraph.

CONCLUSION

The foregoing is submitted as a full and complete response to the rejections in the Office Action mailed May 28, 2010. No additional fees are believed due, however, the Commissioner is hereby authorized to charge any deficiencies which may be required or credit any overpayment to Deposit Account Number 11-0855.

Applicants assert that the claims are in condition for allowance and respectfully request that the application be passed to issuance. If the Examiner believes that any informalities remain in the case that may be corrected by Examiner's amendment, or that there are any other issues which can be resolved by a telephone interview, a telephone call to the undersigned attorney at (404) 745-2473 is respectfully solicited.

Respectfully submitted,

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